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PATENT  
Attorney Docket No. 213026

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Levitsky et al.

Application No. 09/992,443

Art Unit: 1633

Filed: November 16, 2001

Examiner: Sorbello, E.

For: A UNIVERSAL IMMUNOMODULATORY  
CYTOKINE-EXPRESSING BYSTANDER  
CELL LINE AND RELATED  
COMPOSITIONS AND METHODS OF  
MANUFACTURE AND USE

RECEIVED  
JAN 28 2003  
TECH CENTER 1600/2900

RESPONSE TO OFFICE ACTION

Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

In response to the Office Action dated September 10, 2002, please consider the following remarks.

REMARKS

The Present Invention

The present invention is directed to a universal bystander cell line, which is a human cell line, naturally lacks major histocompatibility class I (MHC-I) antigens and major histocompatibility class II (MHC-II) antigens, and is modified by introduction of a nucleic acid molecule comprising a nucleic acid sequence encoding granulocyte macrophage-colony stimulating factor (GM-CSF) operably linked to a promoter. The universal bystander cell line expresses at least 500 ng GM-CSF/10<sup>6</sup> cells/24 hours. The present invention is also directed to a composition comprising the universal bystander cell line and a cancer antigen, a method of making the universal bystander cell line, a method of stimulating an immune response to a cancer in a human patient by administering to the patient the composition, which has been irradiated, and a method of cancer immunotherapy, in which the improvement comprises administering to a human patient having cancer the irradiated composition.